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**TRANSMITTAL LETTER TO THE UNITED STATES
 DESIGNATED/ELECTED OFFICE (DO/EO/US)
 CONCERNING A FILING UNDER 35 U.S.C. 371**

Attorney Docket No. 20256
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 U.S. Application No. (if known,
 371(c)(1)) **10/088535** NW

INTERNATIONAL APPLICATION NO.
 PCT/FR00/02706

INTERNATIONAL FILING DATE
 September 29, 2000

PRIORITY DATE CLAIMED
 October 1, 1999

TITLE OF INVENTION
 ADJUSTABLE GASTRIC IMPLANT

APPLICANT(S) FOR DO/EO/US
 Bruno Longobardi

Applicant herewith submits to the United States Designated Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☒ has been transmitted by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
 - a. ☐ are transmitted herewith (only if not required by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 16 below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ As assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A **FIRST** preliminary amendment.
☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☐ Other items or information:



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PATENT TRADEMARK OFFICE

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17. <input checked="" type="checkbox"/> The following fees are submitted:				CALCULATIONS PTO USE ONLY	
BASIC NATIONAL FEE (37 CFR 1.492 (a)(1)-(5):					
Neither international preliminary examination fee (37 CFR 1.482)					
Nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO					
And International Search Report not prepared by EPO or JPO..... \$1,040.00					
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by EPO or JPO.....\$890.00					
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International preliminary examination fee paid to USPTO (37 CFR 1.482) But all claims did not satisfy provisions of PCT Article 33(1)-(4).....\$710.00					
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ENTER APPROPRIATE BASIC FEE AMOUNT =				\$890.00	
Surcharge of \$130.00 for furnishing oath or declaration later than <input type="checkbox"/> 20 <input checked="" type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$130.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total Claims	8 -20=		X \$18.00	\$	
Independent Claims	1 -3=		X \$84.00	\$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)				\$	
TOTAL OF ABOVE CALCULATIONS =				\$1020.00	
Reduction of ½ for filing by small entity, if applicable. A Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28).				\$	
SUBTOTAL =				\$1020.00	
Processing fee of \$130.00 for furnishing English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$	
TOTAL NATIONAL FEE =				\$1020.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31).				\$	
TOTAL FEES ENCLOSED =				\$1020.00	
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- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 04-0753. A duplicate copy of this sheet is enclosed.
- d. ☐ A payment of \$ _____ is made by credit card. A Credit Card Payment Form (PTO-2038) is attached hereto. The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 CFR 1.16 or any patent application processing fees under 37 CFR 1.17, or credit any over payment to the credit card account shown on the attached Credit Card Payment Form. Refund of all amounts overpaid, including those of twenty-five dollars or less, is specifically requested. Any fees not accepted by the credit card shown on Form PTO-2038 may be charged to Deposit Account No. 04-0753.

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REGISTRATION NUMBER

Dkt. 02056

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Group Art Unit:

BRUNO LONGOBARDI

Examiner:

Serial No.: US National Phase of
PCT/FR00/02706

Filed: concurrently herewith

For: ADJUSTABLE GASTRIC IMPLANT

PRELIMINARY AMENDMENT AND INFORMATION DISCLOSURE STATEMENT

Honorable Assistant Commissioner for Patents
Washington, DC 20231

Sir:

Before calculation of the filing fee, please amend the
above-identified application as follows:

IN THE CLAIMS:

Please amend the claims as set forth hereinbelow and in
the attached appendix:

3. (Amended) A gastric implant according to claim 1,
characterized in that the piece (16), the bag (10), the
overlapping connection means, and the tube (8) are made by
molding.

5. (Amended) An implant according to claim 1,
characterized in that the piece (16) has two end portions
(21-22) extending beyond the bag, with a first one of them

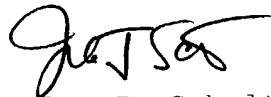
being connected to the tube (8), and in that the overlapping connection means between said end portions comprise at least one series of notches (23) presented by said first portion and a series of D-loops (25) provided set back from the end of the strap opposite to the first end portion.

REMARKS

The claims have been amended to delete all multiple dependencies.

Attached is the search report of the corresponding PCT application, together with copies of the references cited therein, which are listed on the attached Form PTO-1449.

Respectfully submitted,



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Registration No. 28666

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APPENDIXIN THE CLAIMS:

3. (Amended) A gastric implant according to claim 1 [or claim 2], characterized in that the piece (16), the bag (10) , the overlapping connection means, and the tube (8) are made by molding.

5. (Amended) An implant according to claim 1 [or claim 4], characterized in that the piece (16) has two end portions (21-22) extending beyond the bag, with a first one of them being connected to the tube (8), and in that the overlapping connection means between said end portions comprise at least one series of notches (23) presented by said first portion and a series of D-loops (25) provided set back from the end of the strap opposite to the first end portion.

3/1/12

ADJUSTABLE GASTRIC IMPLANT**TECHNICAL FIELD**

5 The invention relates to the field of gastric implants which are fitted around the patient's stomach so as to define a pocket or cavity of relatively small volume in the upper portion thereof which communicates with the remainder of the stomach via a channel or duct which is calibrated by means of the implant.

10 This field corresponds to a method of combating obesity and has been the subject of various technical proposals seeking to achieve local constriction that reduces the stomach's ability to absorb food by surgery acting locally on the stomach.

15

PRIOR ART

Amongst known techniques, it is appropriate to mention the "by-pass" technique which consists in isolating an upper portion of the stomach by means of staples or the like and in connecting this portion to the outlet of the stomach via a by-pass. That technique is referred to by the term "gastric by-pass".

20 In reality, that method constitutes major surgery and can be considered as being irreversible, without its results in terms of weight control being found to be fully satisfactory.

Another method proposed in the prior art, known as "vertical gastropasty", is calibrated by means of a resilient band.

30 Such a method implies defining a channel of small section from the zone where the esophagus and the stomach join by using several rows of staples with an open resilient band at the base of said channel achieving a constriction effect thereon.

35 That kind of surgery gives rise to frequent secondary complications involving a high rate of further

surgery, even though statistics show that food tolerance is mediocre.

A third technique consists in placing an adjustable gastric strap in a high, sub-hiatal position, the strap including a variable-volume cavity engaging the outside wall of the stomach and capable of being filled with a liquid by means of a control box implanted under the skin.

That technique is known as "adjustable gastric banding" and can be considered as providing the best results available at present, for various reasons.

The first is that the surgery can be performed using a celioscope or laparoscope making it possible to benefit from operating conditions that are satisfactory and non-traumatizing. The second is the ease with which the stomach constriction effect can be adjusted by filling the liquid-filled cavity.

To implement such a technique, various proposals have been put forward, and amongst those proposals reference can be made to the teaching of application EP 0 769 282 which relates to a device for reducing a patient's nourishment, which device comprises a flexible but non-stretchable strap of relatively narrow width having a tubular bag of stretchable flexible material secured to one of its faces, generally by adhesive.

The bag is connected by a tube to a box provided with a self-sealing membrane which can be pierced by a syringe needle or the like, thereby enabling a liquid such as physiological serum to be injected or removed so as to control the extent to which the bag is inflated for the purpose of inducing a stomach-constricting effect.

End portions are provided at the ends of the device so as to make it possible to close the strap in the form of a closed loop by connecting its end portions together, thus enabling the bag to contribute to forming the inner peripheral surface of the band.

It can be considered that such a device makes it possible to satisfy the object of localized implantation and constriction of the stomach, but experience has shown up various drawbacks relating to such a device.

5 Firstly, its end portions for enabling the strap to be closed as a loop are not suitable for providing a band of regular shape approximating closely to an ideal circular section. This gives rise to spot concentrations of stresses that subject the stomach wall to localized
10 pressures which can give rise to intolerance phenomena, and even in some cases can be responsible for local puncturing. In addition, the existence of a constriction band of internal section that is not regular is also unfavorable for defining a small-section passage suitable
15 for establishing basically satisfactory transit.

It has also been found, in particular because of its method of manufacture, that an elongate strap that is flexible but not stretchable possesses edges running along its longitudinal sides which are sharp and
20 consequently liable to injure the stomach wall.

It has even been found that these sharp edges can give rise to local puncturing which naturally requires corrective surgery to be performed very quickly.

It has also been found that, because of the sharp
25 edges, connecting the strap and the bag together by means of adhesive can also lead to a risk of the inflated bag being punctured, thus preventing the bag from calibrating the channel and also being responsible for effusion of the inflation liquid, even though this liquid is
30 generally of a physiological kind.

Finally, it should be observed that the nature of the means for interconnecting the end portions cause these means, once they have been connected together, to take up a diverging configuration like the open blades of
35 a pair of scissors, and in this state, said end portions are then often responsible for damaging, irritating, or indeed puncturing the stomach wall.

An object of the present invention is to improve gastric implants of the above type, such improvements together overcoming the drawbacks attached to solutions or embodiments that make use of a strap that is

5 prefabricated separately from a bag and that is connected to the bag by any appropriate means, such as adhesive in particular, as described above.

SUMMARY OF THE INVENTION

10 To achieve the above objects, the gastric implant of the invention is of the type comprising a strap of flexible but non-stretchable material associated with a tubular bag of deformable flexible material, the bag being closed at one end and communicating at its other
15 end with a tube connected to a box including a self-sealing membrane that can be pierced by a needle for injecting and/or removing a fluid to control at will the extent to which the bag is filled, said strap being provided at its ends with complementary end portions
20 enabling the strap to be looped to form a band whose inner peripheral surface is occupied by the bag, said implant being characterized in that:

- the strap is constituted by an elongate piece secured to the inside of the bag and of a width and a thickness that are smaller than the corresponding dimensions of the oblong right cross-section of the bag;
- the piece possesses convex longitudinal edges; and
- complementary overlapping connection means are provided between the end portions of the piece, which means project outside the bag.

Various other characteristics appear from the following description given with reference to the accompanying drawings which show embodiments and implementations of the invention as non-limiting examples.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a diagram showing how the gastric band of the invention is applied.

Figure 2 is a developed plan view of the gastric
5 implant of the invention.

Figure 3 is a side elevation view on line III-III of Figure 2.

Figure 4 is a cross-section view substantially on line IV-IV of Figure 2.

10 Figure 5 is a plan view showing the subject matter of the invention in use.

Figure 6 is a section in elevation through a variant embodiment.

15 Figure 7 is a perspective view showing another variant embodiment.

Figure 1 is a diagram showing how a gastric band given reference 1 is implanted in a high, sub-hiatal position on a stomach 2 so as to define an artificial top gastric pocket 3 which is in communication with a bottom
20 gastric pocket 4 via a communicating channel 5 of through section controlled by the gastric implant 1.

In a known disposition, the gastric implant 1 is constituted in the form of a closed-loop belt or hoop for generating constriction in the stomach wall by means of a
25 bag that is inflatable with liquid, such as physiological serum, that is taken from or inserted into said bag by means of a box 6 possessing a self-sealing membrane 7 which can be pierced by means of the needle of a suitable syringe, or by analogous means. The box 6 is connected
30 to the inflatable bag via a flexible tube 8 of length and flexibility selected to facilitate implantation of the box 6 under the skin. In accordance with the invention, the gastric implant 1 is characterized by a structure of the kind shown in Figures 2 to 4 for the function and use
35 described above.

BEST MANNER OF PERFORMING THE INVENTION

In these figures, the gastric implant 1 comprises a bag 10 of generally tubular shape that is made of a suitable flexible material that is elastically
5 deformable. Selecting this material forms part of the competence of the person skilled in the art.

A first end 11 of the tubular bag 10 is connected to the tube 8, and the bag is closed at its second end 12.

The tubular bag 10 is made in such a manner as to
10 present a right cross-section that is oblong, being defined by two plane sides 13 and 14 which are interconnected by two convex edges 15 occupying the longitudinal edges of the bag between its ends 11 and 12.

In a construction particular to the invention, the
15 bag 10 is associated with an elongate piece 16 constituted by a strap of flexible but non-stretchable material which also presents the feature of being placed inside the bag 10 so as to be connected to the inside face of one of its plane sides, e.g. the side 13 as shown
20 in Figure 4. Selecting an appropriate material to make the strap comes within the competence of the person skilled in the art.

The elongate piece 16 also presents the characteristic of presenting a right cross-section that
25 is oblong in shape, of width ℓ that is less than the width L of the bag 10, and that is preferably substantially equal to the width of one of the plane sides 13 or 14. According to another characteristic, the elongate piece 16 is of thickness e that is less than the
30 distance between the plane sides 13 and 14, and the oblong section which is thus conferred on the strap is defined by two plane faces 17 and 18 which are interconnected by two convex edges 19.

The elongate piece 16 is connected via one of its
35 faces, e.g. the face 17, to the inside surface of one of the plane sides of the bag 10, e.g. the side 13, such that the convex edges 15 and the edges 19 define between

them kinds of half-crescents 20 extending from the plane side 13, whose function is described below.

In accordance with the invention, the above-described structure is obtained as a single piece, e.g.
5 in the form of a one-piece molding.

The elongate piece 16 also presents another structural characteristic which is that of having a first end portion 21 which extends beyond the end 11 of the bag 10, being adjacent, at least in part, to the tube 8 so as
10 to reinforce it. The elongate piece 16 also has a second end portion 22 which extends beyond the end 12 of the bag 10, said end being obtained, particularly when a practically one-piece manufacturing technique is used, by being bonded to the elongate piece 16 by adhesive.

15 Technical means are provided between the end portions 21 and 22 so as to enable them to be connected together with overlap so that the implant is then in the form of a closed band of regular structure that is practically circular and whose inner peripheral wall is
20 occupied, as described below, by the bag 10.

In one embodiment, such connection means comprise notches 23 formed in the longitudinal edges of the first end portion 21, a slot 24 formed through the second portion 22, and at least one, and preferably two, D-loops
25 25 which are set back from the end portion 22, close thereto, while also being set back from the end 12 so as to project transversely from the outside face of the plane side 13. In the example shown, two D-loops 25 are provided, each having the particular feature of defining
30 a kind of bridge of width substantially equal to that of the end portion 21 taken across the bottoms of the notches 23.

The structure of the implant of the invention is characterized by the gastric implant having a shape
35 without any sharp outside edges that might injure the stomach wall because of the way the elongate piece 16 is located inside the bag 10. Furthermore, shaping the

convex edges so as to leave half-crescents enables the bag to deform flexibly while it is being inflated without forming wrinkles or edges that could themselves injure the stomach wall.

5 Finally, as described below, the overlapping connection means between the end portions 21 and 22 hold these portions in a state that lies within the profile of the outer wall of the closed band, thus making it possible to reduce or even eliminate any risk of injuring
10 the stomach wall.

 The gastric implant is put into place as follows.

 With the bag 10 in the deflated state, the end portions 21 and 22 are directed towards each other so that the strap forms a band, a belt, a bracelet, or a
15 hoop of substantially circular section, as shown in Figure 5. This figure shows that the strap constituting the gastric implant is rolled up so that the inflatable bag 10 constitutes the inside surface of the band, with the elongate piece 16 being disposed towards its outer
20 periphery.

 In this situation, the overlapping connection means are implemented to engage the tube 8 and the first portion 21 through the slot 24 of the second end portion 22 so that the excess length of the end portion 21 can
25 then be engaged through the D-loop(s) 25, thus achieving a connection that is firm, but that can be undone, by engaging the D-loops 25 in the notches 23.

 In a preferred disposition it is advantageous, when there are two or more D-loops, for them to be spaced
30 apart in the long direction of the gastric strap in a manner that corresponds to the spacing between two series of notches 23.

 As a result, as shown in Figure 5, the end portions 21 and 22 are connected together with one overlapping the
35 other, thus making it possible firstly to eliminate any projecting and diverging end portions as are to be found in the prior art, and secondly to contribute to forming a

closed band of section that approximates more closely to an ideal circular through section that is favorable for implantation on a stomach wall that is naturally relatively fragile.

5 Once the implant has been put into place, it suffices to engage the needle of a syringe in the box 6 through the membrane 7 and to inject a desired quantity of liquid such as physiological serum into the tube 8 and consequently into the inflatable bag 10 so as to inflate
10 said bag and consequently reduce the through section of the band, which then applies a constriction effect on the stomach wall so as to calibrate the through channel between the sub-hiatal artificial pocket 3 and the main stomach pocket 4.

15 The overlapping connection means between the end portions 21 and 22 can be embodied in various ways, such as that shown in Figure 6, for example. In such a variant, the first end portion 21, in its face 26 facing the face 27 of the second end portion 22 when they
20 overlap, possesses a mutual-engagement shape 28 complementary to a receiving configuration 29 presented by the face 27.

 The shape 28 is arranged in the zone of the end portion 21 close to the end 11 and upstream from the
25 series of notches 23 relative to said end in such a manner as to enable said notches to co-operate with the D-loops 25 when said shape 28 is itself co-operating with the configuration 29.

 Using the above-described means, any risk of
30 aggression, damage, or puncturing due to sharp edges contacting the stomach wall is eliminated to a very great extent, or even completely. Furthermore, when the strap constituting the gastric implant is closed, it forms a band of section that is regular, making it possible to
35 control accurately the through passage presented by the communicating channel between the sub-hiatal artificial pocket 3 and the main stomach pocket 4.

Figure 7 shows another variant embodiment of the overlapping connection means. In this variant, the end portion 21 is provided with one or two spearhead shapes, each spearhead such as 30 presenting two sloping engagement ramps 31 terminating at two shoulders 32 which define, so to speak, the notches 23. This shape facilitates engagement in one or more D-loops 25 while subsequently ensuring that connection is firm and suitable for withstanding the traction stress induced by inflating the bag 10.

The portion 21 is also shaped by a duct 33 for connecting or extending the tube 8 for which a complementary shape 34 is provided in the D-loops 25. Such an embodiment makes it possible to eliminate the end portion 22.

INDUSTRIAL APPLICATION

An advantageous application for the invention lies in making adjustable gastric implants for combating obesity.

The invention is not limited to the examples described and shown since various modifications can be made thereto without going beyond its ambit.

CLAIMS

1/ A gastric implant of the type comprising a strap of material that is flexible but not stretchable associated with a tubular bag (10) of deformable flexible material that is closed at one end (12) and that communicates via its other end with a tube (8) connected to a box (6) having a self-sealing membrane (7) that can be pierced by a needle for injecting and/or removing a fluid so as to control, at will, the extent to which the bag is filled, said strap being provided with means enabling it to be looped in the form of a closed band whose inner peripheral surface is occupied by the bag,

the implant being characterized in that:

- the strap is constituted by an elongate piece (16) secured to the inside of the bag (10) which is shaped to present a right cross-section that is oblong, being defined by two substantially parallel plane sides (13-14) interconnected by two convex edges (15), while the piece (16) has a right cross-section that is likewise oblong, with the greatest width thereof being substantially equal to the width of one of the plane sides (13-14);

- the piece possesses convex longitudinal edges (19); and

- complementary overlapping connection means are provided between the end portions of the strap.

2/ A gastric implant according to claim 1, characterized in that the piece (16), the bag (10), the overlapping connection means, and the tube (8) are made in substantially one-piece manner.

3/ A gastric implant according to claim 1 or claim 2, characterized in that the piece (16), the bag (10), the overlapping connection means, and the tube (8) are made by molding.

4/ An implant according to claim 1, characterized in that the piece (16) is defined by two plane faces (17 and 18) and by two rounded edges (19) and in that said piece is connected to the inside of the bag via one of its plane
5 faces which is coplanar with the inside face of one of the plane sides of the bag.

5/ An implant according to claim 1 or claim 4, characterized in that the piece (16) has two end portions
10 (21-22) extending beyond the bag, with a first one of them being connected to the tube (8), and in that the overlapping connection means between said end portions comprise at least one series of notches (23) presented by said first portion and a series of D-loops (25) provided
15 set back from the end of the strap opposite to the first end portion.

6/ An implant according to claim 5, characterized in that the overlapping connection means comprise, on one of the
20 faces of the first end portion, an engagement shape (28) formed close to the connection zone between the first end portion and the bag, and on the facing face of the second end portion (22), a complementary shape (29).

7/ An implant according to claim 1, characterized in that the overlapping connection means comprise solely an end
25 portion (21) provided with at least one series of notches (23) and extending from one of the closed ends (11) of the strap, together with D-loops (25) provided set back
30 from the second closed end (12) of said strap.

8/ An implant according to claim 7, characterized in that the end portion (21) presents a shape with two spearhead
pieces, defining a duct (33) corresponding to the tube
35 (8), and in that the D-loops (25) are of a shape (34) that is complementary to said duct.

A B S T R A C T

AN ADJUSTABLE GASTRIC IMPLANT

5 Surgery for obesity by implanting a gastric band.
The implant is characterized in that:

- the strap is constituted by an elongate piece (16)
secured to the inside of the bag (10) and of width and
thickness that are smaller than the corresponding
10 dimensions of the oblong right cross-section of the bag;
- the piece possesses convex longitudinal edges; and
- complementary overlapping connection means are
provided between the end portions of the strap.

The invention is applicable to inflatable implants.

15

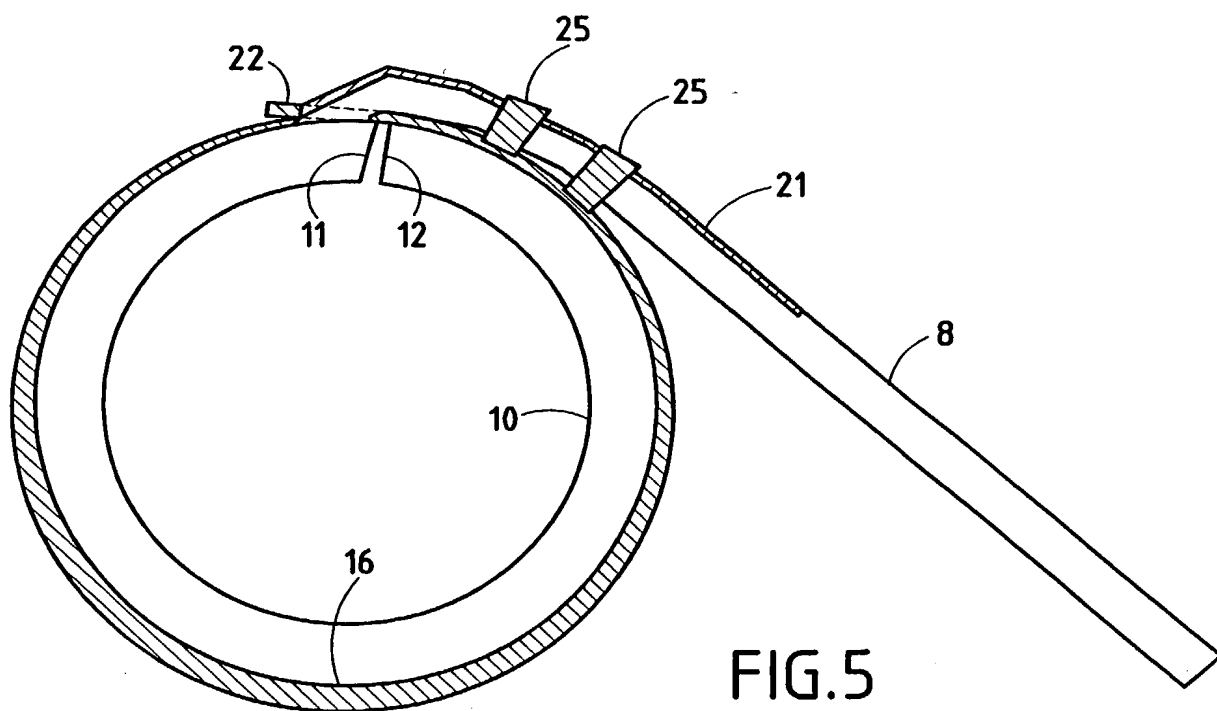
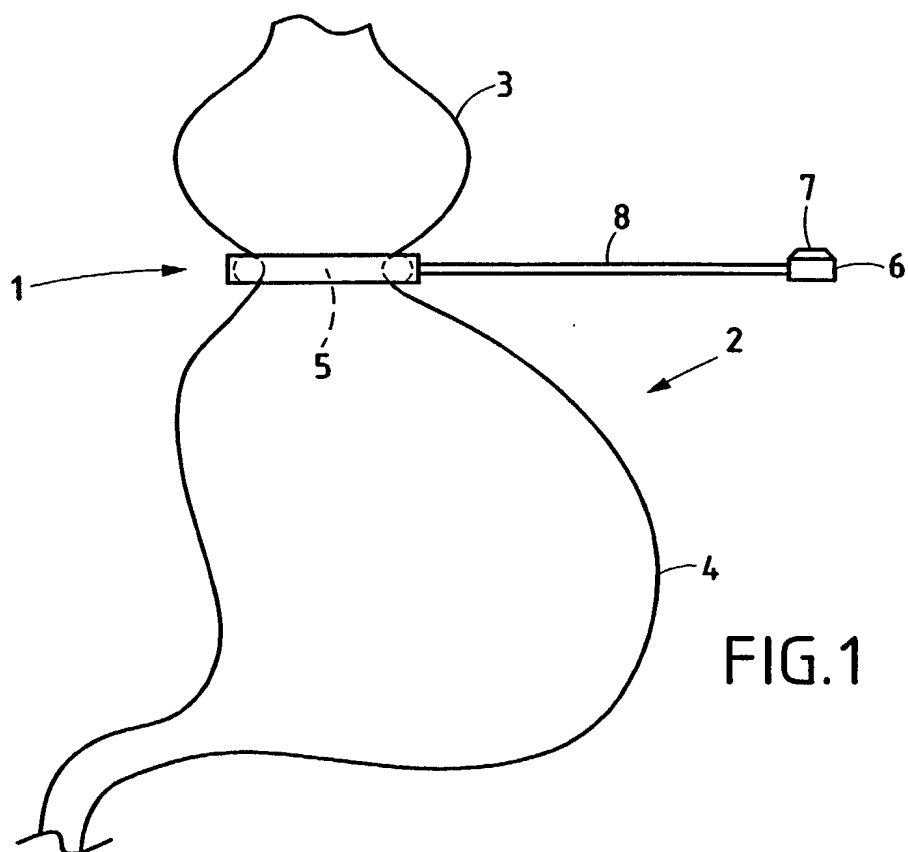
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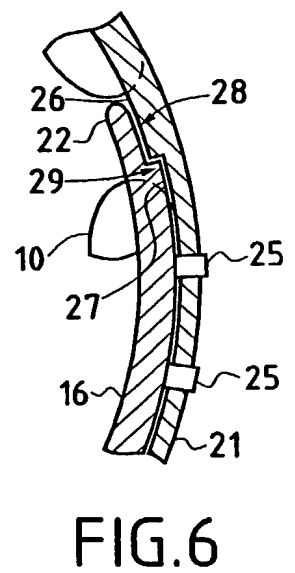
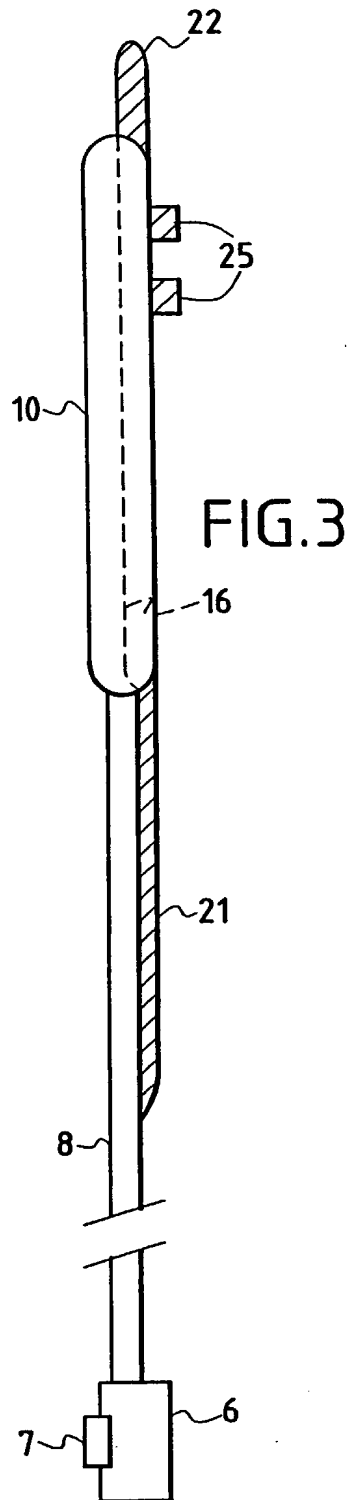
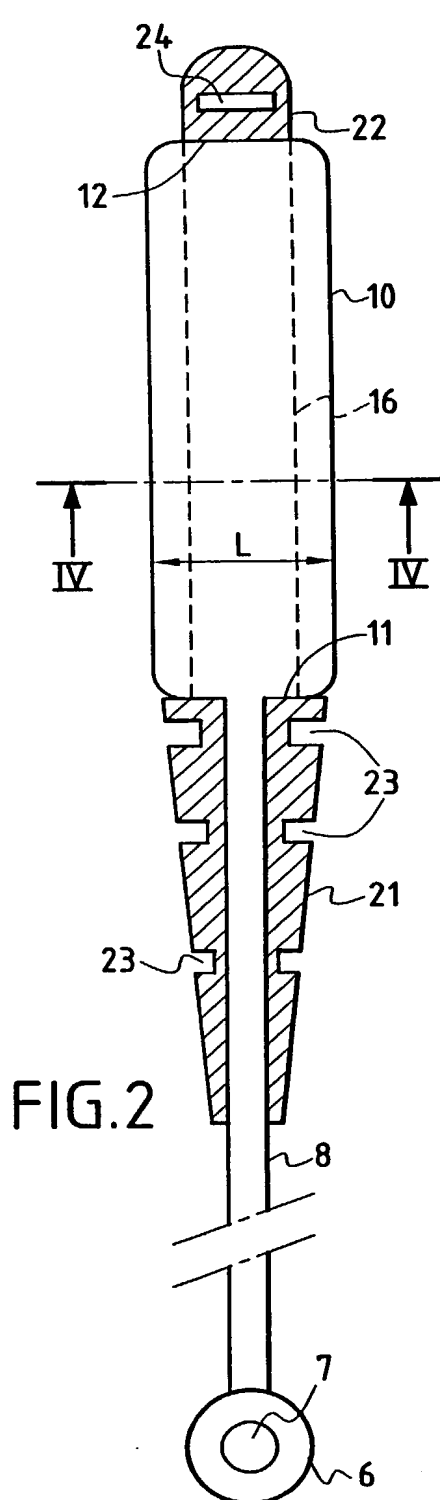
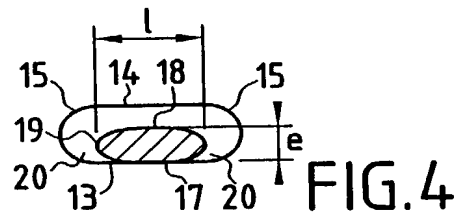
25

30

35 Translation of the title and the abstract as they were when originally filed by the
Applicant. No account has been taken of any changes that may have been made
subsequently by the PCT Authorities acting ex officio, e.g. under PCT Rules 37.2,
38.2, and/or 48.3.

1/3





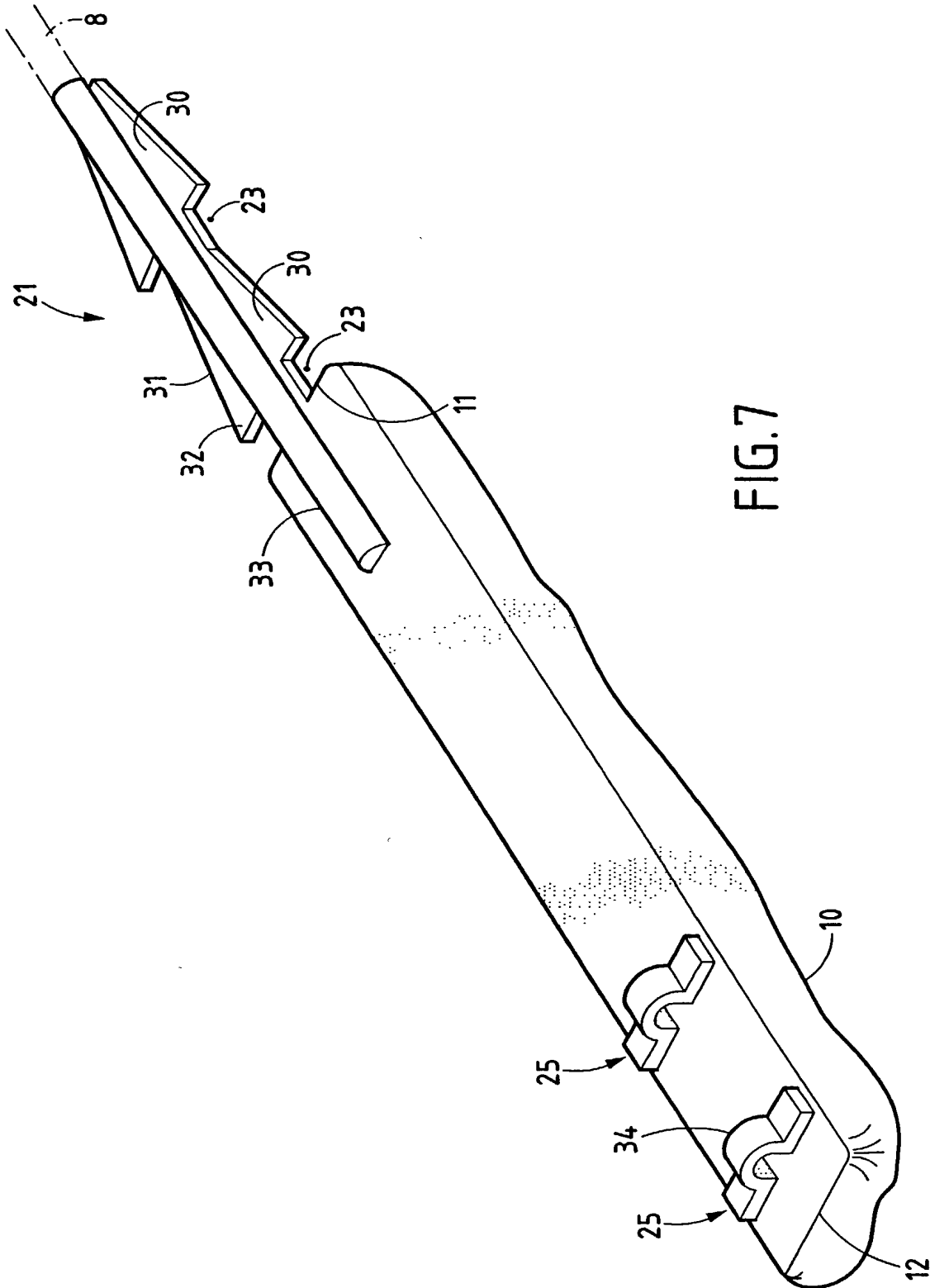


FIG. 7

DECLARATION FOR PATENT APPLICATION

Docket No.

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

ADJUSTABLE GASTRIC IMPLANT

the specification of which

(check one) is described and claimed in PCT International Application **PCT/FR 00/02 706** filed on **29/09/2000**

amended on

(if applicable) (OR)

is described in United States Application

Number

filed on (MM/DD/YYYY)

(OR)

is attached hereto

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

Priority Claimed

99 12 529**FRANCE****01/10/1999****Yes**

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

(Application Serial No.)
a7a-nTo-n-eR1)

(Filing Date)

(Status-patented, pending,

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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